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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,944	11/12/1999	MICHAEL WILLIAM STEWART	T57005US	1063

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WILLIAM J BUNDREN
THE LAW OFFICE OF WILLIAM J BUNDREN
576 FARMINGTON RD, WEST
ACCOKEEK, MD 20607-9796

EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/438,944	Stewart, M. et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *11/2/01 and 11/20/01*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12-14, 17-21, and 29-32* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12-14, 17-21, and 29-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicant's amendment , filed 11/02/2001(Paper No. 15) and 11/23/01 (Paper No. 18), and applicant's declarations, filed 10/11/01 (Paper No.14) and 11-2-01 (Paper No.16) are acknowledged and have been entered. Applicant's amendment ,hand delivered 10-11-01 was not entered as indicated by the notice of a non-responsive amendment mailed 11/2/01 (Paper No. 13).

2. Applicant's application is in sequence compliance.
Applicant's oath, filed 10-11-01 is proper.
Newly added claims 22-25 in Applicant's amendment , filed 11/02/2001(Paper No. 15) have been renumbered by Rule 1.126 as claims 29-32, respectively. It is noted that claims 22-28 as originally filed were canceled in applicant's amendment filed 2-21-01.

3. Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents. The first sentence of the specification should refer to the provisional application using language such as:
This application claims the benefit of PCT/IB/01809, filed 11/10/1999. See MPEP 1302.04.

4. The rejections of record can be found in the previous Office Action, mailed 5-4-01 (Paper No. 11). In view of applicant's amendments, the outstanding rejections have been withdrawn, however a new ground of rejection has been applied.

NEW GROUNDS OF REJECTION

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-14, 17-21 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12-14, 17-21 and 29-32 are drawn to a method of inducing a thrombus in vivo

comprising administering a bifunctional binding agent comprising a targeting component and a component that specifically binds platelets. However, the instant specification provides insufficient guidance and direction in said method regarding the administration of any bifunctional binding agent that comprises a targeting component and a component that specifically binds platelets.

First of all the instant specification provides insufficient guidance and direction regarding the nature of the bifunctional agent administered. The instant specification discloses on page 11, lines 19-22, a method comprising administering a bifunctional agent having an antigenic determinant and a platelet binding site. It is not clear what comprises an antigenic determinant and how a bifunctional agent has an antigenic determinant. Page 16, lines 4-6, discloses that the binding agent is bifunctional preferably functioning as a targeting agent and as a platelet-binding agent. Page 16 discloses that useful bispecific antibodies will have a dual specificity recognizing a selected tumor cell surface antigen on the one hand and recognizing a selected platelet specific agent. However, the instant specification provides insufficient guidance and direction concerning the bifunctional agent.

The instant specification discloses one in vitro assay comprising 3 separate steps in example 8 of incubating tumor cells with tumor specific biotinylated monoclonal antibodies, followed by incubation with avidin, followed by incubation with biotinylated vWF, followed by incubation with blood or platelet rich plasma, which resulted in platelet aggregation around the tumor cells. However it is not clear how this one in vitro assay encompasses use of the recited bifunctional agent. Similarly in a 1.132 declaration filed by applicants, in vivo data illustrating that SCID mice, previously injected with tumor cells that developed palpable tumors, which were administered in succession a biotinylated humanized tumor specific monoclonal antibody, followed by a separate injection of avidin, followed by a separate injection of human biotyinylated VWF, none of which are bifuntional agents, followed by an injection of human platelet rich plasma, showed extensive thrombosis of peripheral tumor vesicles, with no evidence of thrombosis in other tissues of the animal. However, this in vivo data does not correlate with the claimed method of administering any bifunctional agent comprised of any targeting component and any component that binds platelets. Nor does the recited claim language recite injecting platelets after administering an agent, whether said agent is bifunctional or not, as described in said declaration.

Therefore, there is insufficient guidance and direction in the instant specification on how to practice the claimed invention without undue experimentation. Claim 17 lists several components that specifically bind platelets, however it is not clear that all said recited components specifically bind platelets, for example, Bensimon et al (Science 265:2096-2099) teaches that glass binds DNA. Further there is insufficient guidance from the instant specification that any of said listed items (ie glass) when part of a bifunctional binding agent would in fact bind platelets and activate them resulting in thrombus formation.

Regarding claim 19, there is insufficient guidance and direction in the instant

specification that regarding a method comprising a bifunctional agent comprising a targeting component that binds to any ligand /receptor complex encompassed by claims 19-21, because of the lack of guidance of how to make said bifunctional binding agent. Regarding claims 29-32, although the instant specification discloses sites comprising subendothelium, tumor associated antigens, tumor specific antigen and hyperplastic tissue, there is insufficient guidance regarding a method encompassing administration of a bifunctional binding agent relative to a specific site, (see accompanying 112 second rejection).

7.

The following is a quotation of the second paragraph of 35 U.S.C.112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

8. Claims 29-32 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 29-32 are indefinite in the recitation of "wherein the predetermined site" because of the lack of antecedent basis. Claim 12, from which the instant claims depend, does not recite "the predetermined site").

9. No claim is allowed.

10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,

Group 1640, Technology Center 1600
January 25, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644